DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2016

SUGENTECH, INC.
JIYOUNG KWAK
INTERNATIONAL SALES MANAGER
SHINYOUNG PALACE TOWER, 21 HWANGSAEUL-RO 360BEON-GIL,
BUNDANG-GU,SEONGNAM 463-824, KOREA

Re: K142754
Trade/Device Name: Surearly™ Pregnancy Test Strip,
Surearly™ Digital Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: March 30, 2016
Received: April 4, 2016

Dear Jiyoung Kwak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142754

Device Name
Surearly™ Pregnancy Test Strip
Surearly™ Digital Pregnancy Test

Indications for Use *(Describe)*

Surearly™ Pregnancy Test Strip is an in vitro diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

Surearly™ Digital Pregnancy Test is an in vitro diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date of Summary Preparation: March 30, 2016
Reference 510(k) number in process: K142754

1. Submitter Information

Company Name	Sugentech, Inc.
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2. Contact Information

Contact Person	Jiyoung Kwak(Ms.), International Business Manager
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2. Name of Device

Trade Name	Surearly™ Pregnancy Test Strip Surearly™ Digital Pregnancy Test
Common Name	Pregnancy Test
Product Code	LCX / Kit, Test, Pregnancy, Hcg, Over The Counter
Regulation Section	21 CFR §862.1155
Classification Panel	Clinical Chemistry (75)
Device Class	Class II

3. Predicate Device

Trade Name	Clearblue Easy Digital Pregnancy Test
510(k) Number	K060128
Submitter	Unipath Ltd.

4. Device Description

Both Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test are *in vitro* diagnostic medical devices, which use the qualitative assay for the detection of human chorionic gonadotropin (hCG) in urine, as an aid in the early determination of pregnancy. The assays are based on a lateral-flow immunochromatographic assay.

Surearly™ Pregnancy Test Strip is a strip coated with reagents. One end of the strip is a sample pad for urine dipping, and the control and test regions are located in the middle of the strip. Users immerse the sample pad of the strip into the collected urine and see the test results from the colored lines appeared on the strip. The test results are interpreted by users according to the instructions for use.

Surearly™ Digital Pregnancy Test is a digital test reader with a LCD display, combining with an absorbent tip covered by a plastic cap. The absorbent tip that protrudes from the end of the test reader absorbs and delivers urine to reagents on a RAPID type test strip which is located inside a plastic housing of the device. The test reader is automatically switched on, by removing the power film located at the grip. The absorbent tip is placed in urine stream directly or alternatively immersed into the collected urine. The test reader detects the colored lines and shows the digital test result on the display.

5. Intended Use

Surearly™ Pregnancy Test Strip is an *in vitro* diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

Surearly™ Digital Pregnancy Test is an *in vitro* diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

6. Indications for Use

Surearly™ Pregnancy Test Strip is an *in vitro* diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

Surearly™ Digital Pregnancy Test is an *in vitro* diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for over-the-counter (OTC) use only.

7. Comparison to Predicate Device

A summary comparison of the features of the candidate devices (Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test) and the predicate device is provided in Table 5-1 as follows:

Table 5.1 - Comparison table between the candidate devices and the predicate device

Item	Surearly™ Pregnancy Test Strip (Candidate Device 1)	Surearly™ Digital Pregnancy Test (Candidate Device 2)	Clearblue Easy Digital Pregnancy Test (Predicate Device)
510(k) number	–	–	K060128
Format	Test Strip	Test Strip, combined with a digital test reader	Test Strip, combined with a digital test reader
Indications for Use	Over-the-counter hCG test intended for the detection of pregnancy	Over-the-counter hCG test intended for the detection of pregnancy	Over-the-counter hCG test intended for the detection of pregnancy
Test Principle	Lateral-flow immunochromatographic assay	Lateral-flow immunochromatographic assay	Lateral-flow immunochromatographic assay
Sensitivity	25 mIU/mL	25 mIU/mL	25 mIU/mL
Specificity	No interferences with LH, FSH and TSH	No interferences with LH, FSH and TSH	No interferences with LH, FSH and TSH
Specimen	Urine	Urine	Urine
Sample application	Dip	Dip and Stream	Dip and Stream
Sampling time	Dip (5 seconds)	Dip (10 seconds) Stream (5 seconds)	Dip (20 seconds) Stream (5 seconds)

Read time	In 5 minutes	Within 3 minutes	Within 3 minutes
Reading method	Visual reading	Automatic reading with a digital display	Automatic reading with a digital display
Storage	2 - 30℃	2 - 30℃	2 - 30℃
Calibration	WHO 5th International Standard	WHO 5th International Standard	WHO 4th International Standard
Power source	N/A	Battery contained in the device	Battery contained in the device
Electrical safety including EMC	N/A	Confirmed	Confirmed
Mechanical safety	N/A	Confirmed	Confirmed

8. Comparison / Lay-user Studies including menopausal study

8.1 Comparison Study

Comparison studies between the candidate devices (Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test) and comparative method were conducted by lab professionals using total 456 urine samples obtained from 18 to 48 years old women collected from 306 women who were clinically confirmed to be pregnant and another 150 women who were randomly chosen from non-pregnant women.
Among the positive samples, 156 were collected from women who were suspected of being pregnant or pregnant women in their first trimester. The results of the candidate devices demonstrated 100% agreement with comparative method.

8.2 Lay-user (OTC) Study

Total 198 lay users aged 18 to 45 years participated in the lay user study. 100 were non-pregnant women and 98 were pregnant women. The pregnant women were recruited from who might be pregnant or have been confirmed to be pregnant.

For the digital test, both urine midstream and dip procedures were tested as claimed to demonstrate the equivalency of both testing procedures. 100 users tested the digital device using the stream procedure and another 98 users tested it using the dip procedure.

All lay users tested their own urine by themselves with Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test according to the instructions for use in English. The lay users' same urine samples were also tested by professionals.

After the test, lay users were also asked the questions, e.g. whether the test was easy to run, the instructions for use was easy to understand and the test results were easy to read. The results demonstrated that the instructions for use of Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test were understandable and clear enough for lay users, and devices were easy to operate by following the instructions.

8.3 Menopausal Study

Menopausal study was performed with total 510 samples from non-pregnant women to demonstrate to what degree the test devices might have false positive results from women who are not pregnant. (170 samples in pre-menopausal age of 18-40 years old, 170 samples in peri-menopausal age of 41-55 years old, and 170 samples in post-menopausal age over 55 years old).

No false positive result was found and all test results were negative.

9. Other Information about Performance Characteristics and Safety

Further laboratory studies have been carried out for sensitivity/cut-off (including lay user cut-off study), specificity, interference (including pH effect, ethanol and specific gravity ranges), high dose hook effect, precision/reproducibility, and stability to verify the performances of Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test.

These results have demonstrated that Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test perform satisfactorily when used according to the instructions for use.

As the product, Surearly™ Digital Pregnancy Test includes software and electrical components, additional verification and validation activities were also performed. Software validation was performed specifically to ensure the performance of Surearly™ Digital Pregnancy Test electronic read-out result.

The electrical safety including EMC for the test reader was evaluated according to the IEC standards, IEC61010-1:2001 (Second edition), IEC 61010-2-101: 2002 (First edition) IEC 61326-1: 2005, and IEC 61326-2-6:2005. The test reader meets all the requirements of the standards.

10. Conclusions

The overall performance data in this submission supports that Surearly™ Pregnancy Test Strip and Surearly™ Digital Pregnancy Test are safe, effective and substantially equivalent to the predicate, Clearblue Easy Digital Pregnancy test (K060128) which currently marketed in the United States.